

REMARKS

Applicant has amended claim 1 herein. No new matter has been added by the amendment made herein. Entry of the amendment at this time is therefore respectfully requested. Claims 1-26 are presently pending, while claims 1-12 and 15-24 are being examined and claims 13-14, and 25-26 are presently withdrawn.

Claims 1-12 and 15-24 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement for the reasons set forth on pages 2-5 of the present Office Action. Applicant respectfully traverses.

The test for whether a specification has met the written description requirements is whether the specification conveys with reasonable clarity to those skilled in the art that Applicant was in possession of the invention as claimed as of the filing date. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). A description as filed is presumed to be adequate. See MPEP 2163.04.

Finally, it is important to understand that the written description requirement does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998).

Applicant's presently claimed invention is directed to a method of producing an apomictic plant from sexual plants. The method comprises the steps of:

(a) identifying and selecting a first and second sexual plant from an angiospermous plant species, genus, or family, wherein the initiation time of embryo sac formation in the first plant occurs at about the same time as or before meiosis in the second plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues;

(b) hybridizing the first plant and second plant;

- (c) recovering seed therefrom;
- (d) sowing the seed, and
- (e) selecting a hybrid plant that is apomictic.

Applicant fully disclosed and taught this method in the parent application U.S. Application No. 09/576,623, filed May 23, 2000, which has now issued as U.S. Patent No. 6,750,376 and is expressly incorporated by reference. The present application further teaches and provides examples of the presently claimed invention. For example, at pages 22-24 of the Application, it conveniently separates the invention process into four main categories and provides a detailed explanation of each and pages 24-35 of the Specification provide examples to support and provide further detail of each. For instance, Applicant teaches and provides examples of how to identify and select a first and second sexual plants wherein, the initiation time of embryo sac formation in first plant occurs at about the same time as or before megalporogenesis in the second plant – see page 22-23 and Examples 1-6. Example 5 teaches methods of quantifying the divergence in female developmental schedules so that one skilled in the art can appropriately select the first and second plants. Further, in Example 6, Applicant discloses how to obtain greater divergence in female developmental schedules. See also the Examples in the parent application, now U.S. Patent No. 6,750,376.

Applicant not only teaches one skilled in the art how to accomplish this step, but further discloses the importance of the step in producing an apomictic plant from sexual plants – See Table 1 which depicts how asynchronously-expressed duplicate genes cause diplospory and apospory in polyploids containing two genomes divergent in the temporal expression of female developmental schedules. The italicized developmental phases encoded by genome I in Table 1 are skipped because of precociously-expressed check-point genes from genome II. Apomixis occurs because of duplicate genes for megalporogenesis (female meiosis) and embryo sac, embryo, and endosperm formation. The duplicate genes are expressed in the ovule asynchronously, such that embryo sac formation preempts megalporogenesis, resulting in a genetically unreduced (maternal) embryo sac (containing an unreduced egg), and embryo formation which further preempts fertilization, resulting in a parthenogenically produced embryo, i.e., an apomictic seed.

Applicant further discloses and teaches in the Specification plant breeding methods to obtain germplasm for producing apomictic plants from sexual plants when appropriate degrees of

divergence in female developmental schedules does not exist among currently available varieties or lines --- see last paragraph of page 22 of the Application.

Specifically, the disclosure sets forth Applicant's method of identifying and hybridizing sexual plants by identifying and selecting a first and second sexual plant wherein the initiation time of embryo sac formation in the first plant occurs at about the same time as or before megalporogenesis in the second plant. The Specification further discloses hybridizing the selected first and second plants that were specifically identified having divergent ovule development schedules and teaches how to determine the timing of megalporogenesis by using cytoembryologically techniques.

In contrast to the prior art, Applicant first discovered and taught that apomixis is not caused by one or two apomixis genes, but in fact is caused by the asynchronous expression of many duplicate genes regulating meiosis and seed development, leading to the presently claimed method. Applicant provides in the Specification a working example of quantifying divergence in female development schedules with *Tripsacum* as set forth in Example 5.

Further, Applicant submits a 1.132 declaration, which is attached hereto. In the Declaration, Dr. Carman disclosed that apomixis was obtained in both dicotyledonous (*Antennaria*) and monocotyledonous (*Sorghum* and *Tripsacum*) plants using the methods described and claimed in the present application. This provides yet additional evidence that Applicant fully disclosed the invention in such a way that it conveys with reasonable clarity to those skilled in the art that Applicant was in possession of the invention as claimed.

Applicant's presently pending claims are drawn narrowly and specifically to a method which requires the specific identification and selection of first and second sexual plants divergent in the expression of female developmental schedules such that initiation time of embryo sac formation in the first plant occur at about the same time as or before megalporogenesis in the second plant followed by hybridizing the first and second plants.

As pointed out in detail above, the present application along with the parent application U.S. Application No. 09/576,623, filed May 23, 2000, which has now issued as U.S. Patent No. 6,750,376, reasonably teach one how to distinguish plants having divergent initiation times of embryo sac formation. Example 5 specifically teaches methods of quantifying the divergence in female developmental schedules so that one skilled in the art can appropriately select the first

and second plants and Example 6 teaches one skilled in the art how to obtain greater divergence in female developmental schedules.

Further, contrary to the Examiner, the present disclosure also teaches procedures for determining Expression of Apomixis. See page 24 of the Specification as filed. With these techniques and procedures, one skilled in the art would easily be able to determine whether a plant was facultatively apomictic or not.

Again, a description as filed is presumed to be adequate. As stated above, the written description requirement does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.

Thus, in view of Applicant's disclosure of the invention and the working examples showing adequacy of the disclosure, one skilled in the art would reasonably conclude that the inventor had possession of the claimed invention at the time of filing. Applicant therefore respectfully requests that the rejection for lack of written description be removed.

Claims 1-12 and 15-24 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirements for the reasons set forth on pages 5-8 of the Office Action. Applicant respectfully traverses.

The test of enablement is whether the "disclosure coupled with information known in the art provides sufficient information to one reasonably skilled in the art to make or use the invention without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, (Fed. Cir. 1988). Reasonable and routine experimentation is not undue experimentation. In fact, even if the experimentation is complex it does not necessarily make it undue, if the art typically engages in such experimentation. *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104 (Fed. Cir. 1985).

There are many factors to be considered when determining whether any necessary experimentation is "undue." These factors include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). It is improper to

conclude that a disclosure is not enabling based on only one of the above factors. MPEP § 2164.01 (a).

First, the Examiner states that the Specification does not provide any guidance regarding any angiospermous plants wherein the initiation time of embryo sac formation in the first plant occurs at about the same time as or before megalporogenesis in the second plant relative to the developmental maturity of the nongametophytic ovule and ovary tissues in terms of their genetic, morphological and/or physiological characteristics. The Examiner further states that the Specification does not provide guidance of how one would distinguish plants having divergent initiation times of embryo sac formation.

Applicant respectfully disagrees and points out that the present application does in fact provide examples and guidance of identifying and selecting a first and second plant. Applicant provides examples and specific direction of identifying and selecting first and second plant having divergent female reproductive schedules such that the initiation time of embryo sac formation in the first plant occurs at about the same time as or before megalporogenesis in the second plant. For instance, page 22-23 and Examples 1-6.

In Example 5, Applicant teaches methods of quantifying the divergence in female developmental schedules so that one skilled in the art can appropriately select the first and second plants. Further, in Example 6, Applicant discloses how to obtain greater divergence in female developmental schedules. See also the Examples in the parent application, now U.S. Patent No. 6,750,376. While routine effort is required to use Applicant's presently claimed method, no undue experimentation is required. The steps of the method are clear and predictable. Applicant provides detailed direction of how to identify or produce the required divergence between the plants. No undue experimentation is required, simply routine lab work and effort following the instructions provided by Applicant.

Applicant further provides a working example of quantifying and identifying the required divergence in female development schedules. In Example 5, Applicant illustrates this step of the method with *Tripsacum*. Example 3 also is a working example of quantifying effects of different photoperiods on flowering, with *Antennaria* species used in the example. FIGS. 3 and 4 of the Specification both show actual examples as well.

Additional working examples were provided in the 1.132 Declaration of John G. Carman, filed February 9, 2001. As mentioned above, Dr. Carman discloses in the Declaration that

apomixis was obtained in both dicotyledonous (*Antennaria*) and monocotyledonous (*Sorghum* and *Tripsacum*) plants using the methods described and claimed in the present application. In three attempts, Dr. Carman successfully obtained apomictic hybrids all three times, providing strong evidence that one skilled in the art is enabled by the Applicant's teachings and disclosure to use the presently claimed method without undue experimentation.

Further, the present disclosure also teaches procedures for determining Expression of Apomixis at page 24 of the Specification as filed. With these techniques and procedures, one skilled in the art would easily be able to determine whether a plant was facultatively apomictic or not.

The Examiner alleged that this art is unpredictable because the resulting plants may be genetically unstable and unpredictable to select apomictic plants on the basis of distinct maternal morphological types among the progeny of a cross. The Examiner cites de Wet as teaching that breeding for apomixis by sexual hybridization with a group of species of related groups of species is unpredictable because the resulting plants may be genetically unstable and unpredictable to select apomictic plants on the basis of distinct maternal morphological types among the progeny of a cross.

Applicant respectfully disagrees. The rejection applies a view of the field that existed prior to but not after the inventor's breakthrough discovery and teachings that by identifying and hybridizing a first and second sexual plant having divergent reproductive schedules of ovule development such that the initiation time of embryo sac formation in the first plant occurs at about the same time as or before meiosis in the second plant an apomictic plant could be produced. In particular, the inventor achieved production of apomictic plants using routine techniques applied in a specific way as taught by Applicant based on his surprising discovery that asynchronous expression of ovule development such that embryo sac formation preempts meiosis will result in a genetically unreduced (maternal) embryo sac (containing an unreduced egg), and embryo formation which preempts fertilization, resulting in a apomictic production.

Further, the citing of Bashaw and Bates to support a claim of unpredictability by the Examiner is also flawed as it applies a view of the field that existed prior to Applicant's discovery, which Applicant sets forth in detail in the application and examples. The present application contains a thorough explanation of how the present duplicate-gene asynchrony

approach to making apomictic plants is consistent with the observations that have been made in the apomixis field over many years and further explains why the theories and assumption of the prior art are deficient. Once it is understood by a person skilled in the art of plant breeding how apomixis arises, it is a routine matter to produce apomictic plants using the disclosed method, even though lab effort and work is required to carry out the directions provided of Applicant herein.

In view of the above, one skilled in the art could use the invention based on the disclosure and examples provided by Applicant without undue experimentation. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Claim 1 was rejected for nonstatutory obviousness-type double patenting in view of claim 14 of U.S. Patent No. 6,750,376. Applicant submits herewith a timely filed terminal disclaimer. Thus, this rejection is now moot and should be withdrawn.

In view of the above amendments and arguments, Applicant now believes all claims to be in condition for allowance. If there are any questions, the Examiner is invited to call Applicant's representative Rodney Fuller at (602) 916-5404 to resolve any remaining issues to expedite the allowance of this application.

Respectfully submitted,

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Date

/Rodney J. Fuller/
Rodney J. Fuller (Reg. No. 46,714)

FENNEMORE CRAIG
Customer No. 27,887

602-916-5404